Complete Summary

GUIDELINE TITLE

Practice parameter: temporal lobe and localized neocortical resections for epilepsy: report of the Quality Standards Subcommittee of the American Academy of Neurology, in association with the American Epilepsy Society and the American Association of Neurological Surgeons.

BIBLIOGRAPHIC SOURCE(S)

Engel J Jr, Wiebe S, French J, Sperling M, Williamson P, Spencer D, Gumnit R, Zahn C, Westbrook E, Enos B. Practice parameter: temporal lobe and localized neocortical resections for epilepsy. Epilepsia 2003 Jun;44(6):741-51. [69 references] PubMed

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COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Disabling complex partial seizures associated with epilepsy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Neurological Surgery
Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To address published evidence on the safety and efficacy of localized resective surgery, either temporal or neocortical, as treatment for uncontrolled complex partial seizures
- To address the following questions:
    - What is the effectiveness of anteromesial temporal lobe and localized neocortical resections as a treatment for disabling complex partial seizures with respect to seizure recurrence, quality of life, and activities of daily living?
    - What is the risk of complications from these surgical interventions, compared with the efficacy and risks of continued pharmacotherapy?

TARGET POPULATION

Patients with uncontrolled disabling complex partial seizures

INTERVENTIONS AND PRACTICES CONSIDERED

1. Anteromesial temporal lobe resection
2. Localized neocortical resection

MAJOR OUTCOMES CONSIDERED

- Effectiveness of anteromesial temporal lobe and localized neocortical resections as a treatment for disabling complex partial seizures with respect to seizure recurrence, quality of life, and activities of daily living
- Risk of complications from anteromesial temporal lobe and localized neocortical resections, compared with the efficacy and risks of continued pharmacotherapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The initial comprehensive literature search was performed by the University of Minnesota, using Medline and Current Contents to identify all relevant papers published between January 1, 1990 and June 1999. Two lists of search terms were used, and at least one term from each list needed to be present for a paper to be identified. The first list included the following terms: seizures, epilepsy, Lennox-Gastaut, West syndrome, infantile spasms, Landau-Kleffner, hypothalamic hamartoma, cortical dysplasia, hemimegencephaly, tuberous sclerosis. Sturge-Weber, Rasmussen's encephalitis, mesial temporal sclerosis, hippocampal sclerosis, and drop attacks. The second list included the following terms: surgery, amygdalohippocampectomy, multiple subpial transection, lobectomy, corticectomy, corpus callosotomy, corpus callosum transection, amygdalotomy, hemispherectomy, and resection.

Three panel meetings were held. At the first meeting, in December 1997, it became apparent that only papers that reported series with pure anteromesial temporal lobe resections, pure localized neocortical resections, or both, were sufficiently numerous to analyze. For the purposes of this review, no distinction was made among the various types of anteromesial temporal resections performed, which ranged from selective amygdalohippocampectomy to large tailored anterior temporal lobe excisions. All patients included in this initial review underwent surgery for what was considered to be medically refractory complex partial seizures with or without secondarily generalized seizures.

At the second meeting in December 1998, inclusion criteria for published surgical series were further refined to make sure results would be as generalizable as possible to all temporal lobe and neocortical resections. For anteromesial temporal lobe resections, papers were excluded if the study population was limited to only a subset of a larger population of patients who ordinarily would be considered for this surgical procedure. For instance, papers were excluded when they included only patients with tumors on magnetic resonance imaging (MRI), only patients with bilateral independent electroencephalogram (EEG) spikes, only patients who had invasive recording, or only children or the elderly. Because exclusively pediatric studies were not included and data were not analyzed by age, this review has limited applicability to children. For localized neocortical resections, exclusion criteria were similar, except that series devoted entirely to frontal lobe or occipital lobe resections were permitted.

Two specific postoperative outcome measures were chosen: frequency of epileptic seizures other than auras (simple partial seizures without motor features), and quantitatively measured health-related quality of life (QOL). The majority of papers used a standardized seizure outcome classification system with minor variations, which identified patients who were free of disabling seizures (and therefore permitted persistent auras), improved, and not improved (accepting whatever standard the investigators used to differentiate these latter two groups). The evaluation periods varied and it was not possible to segregate outcome results according to all the various periods of follow-up reported. Data were also used from the few papers that did not use this standardized scale when it was at least possible to segregate patients who were free of disabling seizures from those who were not. Papers that included other outcome measures regarding psychiatric status, work, school, neurocognitive function, driver's licensing, and mortality were also reviewed. Finally, all papers included in the study were evaluated for data that would reveal the incidence and nature of surgical complications.

Papers were ranked according to class of evidence. In the initial review there were no Class I reports. One would have met criteria for Class II and the remainder for Class III, except that none had a masked outcome assessment; therefore, all were Class IV. Papers were further evaluated according to a rating scale designed to eliminate papers with less reliable data and to permit stratification of the remainder at a later date, if desired, according to criteria that might influence the results of the evaluation. The content, validity, and relevance of the rating scale were addressed by scoring a large number of articles and by panel discussion. Based on this rating scale, series were excluded if they contained fewer than 20 patients, if the outcome assessment was unclear, if the surgical intervention was adequately described, or if any patients in the series underwent surgery before 1974, when modern neuroimaging was not generally available. For all outcome assessments, series were excluded if follow-up for any patients was less than 1 year. Of particular interest for later stratification were series in which all patients underwent surgery after 1985, when magnetic resonance imaging was widely available, and series in which all patients had at least 2 years of follow-up.

At the third meeting in August 1999, the rating scale was used to select those papers that would make up the data set from 171 papers that remained from the University of Minnesota search, and 2 others added as a result of independent searches carried out by the panelists. In order to avoid overlapping data reported more than once from the same center, when two or more papers from the same center met the inclusion criteria, only the largest or most recent study was used for each specific review objective. If several papers from the same center recorded results of patient populations that were overlapping, one paper might be used for one review objective, while a different paper might be chosen for another review objective.

A final literature search, through September 2001, for new studies meeting Class I criteria yielded one randomized controlled trial of surgery for temporal lobe epilepsy with a masked outcome assessment, published in August 2001. Results of this study were essentially identical to those obtained from the earlier literature review.

NUMBER OF SOURCE DOCUMENTS

The initial search yielded 1282 citations. After reviewing the abstracts, 415 were considered to contain potentially usable information for this study and were reproduced in full. A final literature search yielded an additional randomized controlled trial.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification Scheme for a Therapeutic Article

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population.

The following are required:

a. Primary outcome(s) is/are clearly defined.
b. Exclusion/inclusion criteria are clearly defined.
c. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias.
d. Relevant baseline characteristics are presented and substantially equivalent among treatments groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a randomized, controlled trial in a representative population that lacks one criterion a-d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Seizure outcomes were analyzed for anteromesial temporal lobe resections and for localized neocortical resections separately. In addition, data were obtained for quality of life (QOL) outcome, other outcomes affecting activities of daily living, and surgical complications. Data for seizure outcome were categorical. When possible, these data were pooled. Because each study reported more than one outcome (e.g., free of disabling seizures, improved and not improved), weighted averages were obtained by weighing each proportion by the study sample size. The results of the Class I study are not included in the original data set. They are reported separately and in detail, first, as the primary evidence for establishing these guidelines.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Translation of Evidence to Recommendations

Level A rating requires at least one convincing Class I study or at least two consistent, convincing Class II studies.

Level B rating requires at least one convincing Class II study or overwhelming Class III evidence.

Level C rating requires at least two convincing Class III studies.

Rating of Recommendation

A = established as useful/predictive or not useful/predictive for the given condition in the specified population.

B = useful/predictive or not useful/predictive for the given condition in the specified population.

C = possibly useful/predictive or not useful/predictive for the given condition in the specified population.

U = data inadequate or conflicting. Given current knowledge, test/predictor is unproven.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft guidelines were reviewed for accuracy, quality, and thoroughness by the American Academy of Neurology (AAN) members, topic experts, and pertinent physician organizations.

Final guidelines were was approved by the Quality Standards Subcommittee on April 16, 2002, the Practice Committee on August 3, 2002, and the American Academy of Neurology Board of Directors on October 19, 2002. The report was published in Neurology 2003;60:538-547.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the recommendation ratings (A, B, C, U) and classifications of the evidence (Class I through Class IV) are provided at the end of the "Major Recommendations" field.

Recommendations

1. Patients with disabling complex partial seizures, with or without secondarily generalized seizures, who have failed appropriate trials of first-line antiepileptic drugs should be considered for referral to an epilepsy surgery center, although criteria for failure of drug treatment have not been definitely established (A)
2. Patients referred to an epilepsy surgery center for the reasons stated above who meet established criteria for an anteromesial temporal lobe resection and who accept the risks and benefits of this procedure, as opposed to continuing pharmacotherapy, should be offered surgical treatment. (A)
3. There is insufficient evidence at this time to make a definitive recommendation as to whether patients with a localized neocortical epileptogenic region will benefit or not benefit from surgical resection. (U)

Definitions:

Rating of Recommendation

A = established as useful/predictive or not useful/predictive for the given condition in the specified population.

B = probably useful/predictive or not useful/predictive for the given condition in the specified population.

C = possibly useful/predictive or not useful/predictive for the given condition in the specified population.

U = data inadequate or conflicting. Given current knowledge, test/predictor is unproven.

Classification Scheme for a Therapeutic Article

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population.

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a. Primary outcome(s) is/are clearly defined.
b. Exclusion/inclusion criteria are clearly defined.
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d. Relevant baseline characteristics are presented and substantially equivalent among treatments groups or there is appropriate statistical adjustment for differences.

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Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- These guidelines may assist physicians in making appropriate clinical decisions regarding using temporal lobe and localized neocortical resections for epilepsy.
- One intention-to-treat randomized controlled trial of surgery for mesial temporal lobe epilepsy found that 58% of patients randomized to be evaluated for surgical therapy (64% of those who received surgery) were free of disabling seizures and 10 to 15% were unimproved at the end of 1 year, compared with 8% free of disabling seizures in the group randomized to continued medical therapy. There was a significant improvement in quantitative quality-of-life scores and a trend toward better social function at the end of 1 year for patients in the surgical group, no surgical mortality, and infrequent morbidity. Studies indicated that the benefits of anteromesial temporal lobe resection for disabling complex partial seizures is greater than continued treatment with antiepileptic drugs, and the risks are at least comparable.

POTENTIAL HARMS

- Surgery can result in complications, death, new neurologic deficits, postoperative infections, and cognitive and behavioral changes.
- The risks associated with anteromesial temporal lobe resection for disabling complete partial seizures are comparable with the risks associated with continued treatment with antiepileptic drugs.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology, the American Epilepsy Society, and the American Academy of Neurological Surgeons. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology, American Epilepsy Society, and American Academy of Neurological Surgeons recognize that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Feb 25

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society
American Association of Neurological Surgeons - Medical Specialty Society
American Epilepsy Society - Disease Specific Society

GUIDELINE DEVELOPER COMMENT

The American Epilepsy Society, in collaboration with the Quality Standards Subcommittee of the American Academy of Neurology, appointed a panel to develop practice parameters for surgical treatment of epilepsy. The American Association of Neurological Surgeons subsequently agreed to join this project. The core-working group consisted of four neurologists who were directors of epilepsy centers that offered surgical treatment, a neurosurgeon who was director of an epilepsy surgery program, and a neurologist with particular expertise in outcomes research. Additional panelists included two members of the Quality Standards Subcommittee, one of whom was an epileptologist and another who was not; a neurologist who was director of an epilepsy program for a health maintenance organization; and a general neurologist.

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Quality Standards Subcommittee Members: Gary Franklin, MD, MPH (Co-Chair); Catherine Zahn, MD (Co-Chair); Milton Alter, MD, PhD; Stephen Ashwal, MD; Richard M. Dubinsky, MD; Jacqueline French, MD; Michael Glantz, MD; Gary Gronseth, MD; Deborah Hirtz, MD; Robert G. Miller, MD; James Stevens, MD; and William J. Weiner, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology.

Electronic copies: Available from the American Academy of Neurology Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 11, 2004.

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